

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



# (12) UK Patent Application (19) GB (11) 2 301 350 (13) A

(43) Date of A Publication 04.12.1996

(21) Application No 9612692.5

(22) Date of Filing 18.06.1996

(30) Priority Data

(31) 9512730

(32) 22.06.1995

(33) GB

(71) Applicant(s)

**Bristol-Myers Squibb Company**

**(Incorporated in USA - Delaware)**

**P.O.Box 4000, Princeton, New Jersey 08543-4000,  
United States of America**

(72) Inventor(s)

**John Arthur Gooch Gent**

**Graham Emery Steer**

(74) Agent and/or Address for Service

**D Young & Co**

**21 New Fetter Lane, LONDON, EC4A 1DA,  
United Kingdom**

(51) INT CL<sup>6</sup>

**C02F 1/00 , A61F 5/44**

(52) UK CL (Edition O )

**C1C CACX C230 C253 C254 C31X C332 C460**

(56) Documents Cited

**None**

(58) Field of Search

**UK CL (Edition O ) C1C CACX CRCX CSCX CTCX**

**INT CL<sup>6</sup> C02F**

**ONLINE: WPI**

(54) **Method and formulation for absorbing and treating waste**

(57) A method of treating waste is described. The method includes contacting wet or moist excretions from animals, such as from humans, with a formulation which will retard the rate of decomposition of the excretions, and absorb liquid therefrom. It is useful to ostomates and to those suffering incontinence. The formulation includes 100 parts by weight superabsorbent, 0.5 to 6 parts by weight water and 5 to 30 parts by weight glycerol.

GB 2 301 350 A

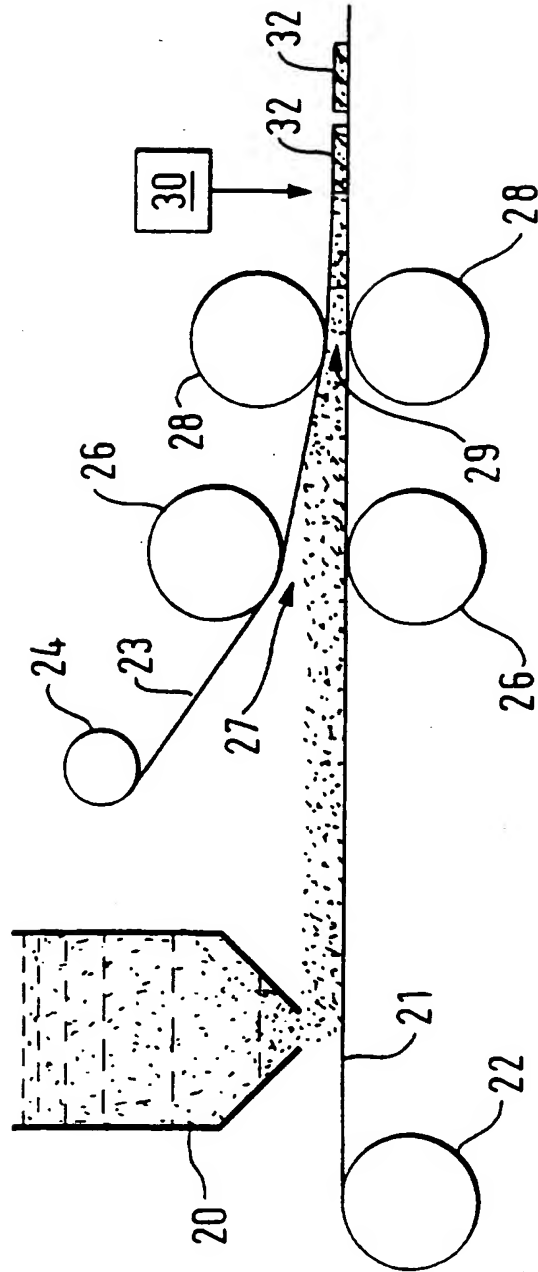


FIG. 1

METHOD AND FORMULATION FOR ABSORBING  
AND TREATING WASTE

5       The present invention relates to a method and formulation for converting a superabsorbent powder into a coherent mass as a strip, pad or tablet which may be utilised to absorb products such as body waste.

10       When materials are excreted from the body of an animal, they usually contain partially decomposed foods and bacteria. When the excretions leave the body, decomposition will continue to proceed. The products of decomposition will depend upon the nature of the foodstuffs and the agents of decomposition, such as bacteria and enzymes. In most cases the products of decomposition will include gases. It would be highly desirable to control this decomposition.

15       UK Patent (GB-A)1595687 discloses a method of treating excretions with a composition comprising a thickening agent based on (meth)acrylic acid, a hydrophilic adsorption agent and a perfume. The composition masks odours from excrements. Another suggestion for dealing with excrements has been made in US Patent 4179367. Other proposals have been made in UK Patents Nos. 1 332 066 and 1 396 210, US Patent No. 4 605 401, EP 33235, EP 604103 and PCT WO81/02891 and WO93/22048.

20       In the case of ostomy pouchs and in particular ileostomy pouches, the excreted waste contained therein is only partially decomposed when it leaves the body. The excreted components which are of a composition akin to soup or loose slurry, are maintained at or near body temperature, by virtue of being contained in a pouch immediately adjacent to the skin, and hence the temperature conditions are suitable for further decomposition to occur and the formation of gases. The continued evolution of gases will in the extreme case, lead to the pouch becoming excessively pressurised and detaching itself from the body, or in the case where the pouch contains a vent incorporating a gas filter will lead to premature failure of the filter system, and in turn lead to the release of malodorous gases.

30       None of the prior art documents provides a satisfactory solution to the problem of how to effectively retard or control in the decomposition of excretions in the context of a person obliged to wear an ostomy pouch.

It has been found that the compression forces to form a tablet containing a high level of superabsorbent powder (in excess of 60%) are very high and using

conventional tableting machines are limited to tablets having a weight of about 3 grams. The resultant tablets are friable i.e. shed particles, are prone to gel-lock (incomplete breakdown) and have a slow rate of breakdown in aqueous products such as body waste. It is the purpose of this invention to overcome the aforementioned disadvantages and to enable the production of both tablets and flat continuous sheets containing high levels of superabsorbent.

According to a first aspect of the present invention there is provided a formulation disposed in an ostomy or ileostomy pouch intended to retard the rate of decomposition of the excretions and which essentially comprises 100 parts by weight (pbw) superabsorbent, from 0.5 to 6 pbw water, from 5 to 30 pbw glycerol, from 0 to 5 pbw internal mould release agent, and from 0 to 50 pbw preservative or compounds having similar effect.

The above formulation may be provided in tablet form. The tablet may but need not include a preservative. Preferably when the formulation is to be delivered in tablet form, it comprises 6 to 15 pbw (instead of 5 to 25 pbw) of glycerol. The tablet may also include a tablet disintegrant, an internal mould release agent, and optionally, an inert filler. Preferably the preservative and the superabsorbent material are present in the same tablet.

Preferably the preservative mainly comprises sodium benzoate and/or sodium nitrite.

The superabsorbent comprises a water-swellaable polymer.

Preferably the superabsorbent comprises sodium polyacrylate and is in the form of a powder having a maximum particle size of 850 microns and preferably less than 425 microns.

The invention in a preferred embodiment solves the problem of how to retard the decomposition of excretions by contacting the excretions after leaving the body with a formulation containing a component or components which will significantly reduce the rate at which excreted materials will continue to decompose. Thus the present invention reduces *inter alia* odour problems and gas generation or management problems.

According to a second aspect of the invention, a method of making a flat article such as a sheet or pad comprises:

- (i) providing a formulation comprising  
100 pbw superabsorbent,  
0.5 to 6 pbw water,  
5 to 30 pbw glycerol; and  
0 to 50 pbw preservative or compound having similar effect;
- (ii) pressing the said formulation without the application of heat between two flat platens at a pressure in the range 0.02 to 2 tonnes per sq. cm.; or alternatively, forming a sheet between one or more pairs of rollers with or without upper and lower confining sheets or films, to yield a continuous sheet which may subsequently cut into the desired size.

It is preferred that at least one of the confining sheets or films has a high degree of permeability to air. An example of such a sheet is tissue paper.

The resulting products are particularly useful when placed in an ostomy pouch or an ileostomy pouch to absorb liquid and minimise release of malodorous gases. They also have the advantage that shedding of dust or particles is substantially avoided, and that no heating step nor the inclusion of adhesive is needed. A prior proposal aimed at providing an effective absorbent article required the use of hot-melt adhesives, which significantly complicated the manufacturing process. The present invention does not encounter such problems.

Reference has been made in this specification to the inclusion of glycerol as a component of the formulation according to the invention. Glycerol is but one example (although currently the preferred example) of a component which enables the advantages of the invention to be achieved. For glycerol could be substituted a non-volatile lubricious polyhydroxy compound which is water-soluble or water-dispersible at or below 40°C and is liquid at room temperature (15 to 20°C).

It has been surprisingly found that by mixing a blend of glycerol and water into a superabsorbent powder, it has been found possible to produce a free flowing powder, which on subsequent exposure to pressure forms a coherent structure. Said structure on being contacted by aqueous matter, will readily absorb said liquids to form a gel.

One advantage of an embodiment of the present invention is that the inclusion of a preservative in the formulation, such as one normally used in the preservation

of food before ingestion, retards the rate of decomposition of wet or moist excretions from animals, such as from humans, when the preservative is contacted with the excretions after they have left the body. Hence, the use of a preservative or compounds having similar effects will reduce the rate at which gases are evolved from the excretions, and hence reduce odour problems.

The finding that preservatives can be used, in one embodiment of the invention, to retard, or even prevent, the continuing decompositions of wet or moist excretions is very surprising. This is because it was completely unexpected that by contacting the wet excretions of animals with materials used in the preservation of food, one could achieve a significant reduction in the volume of gas evolved *via* the decomposition of such excretions.

A further advantageous finding is that the level and odour of the wet excretions of animals could be further reduced by the incorporation of water swellable polymers in combination with the preservative. In this regard, the water swellable polymers form a gel-like structure and so reduce the fluidity of the excrement. This has the additional advantage that when a gas vent is incorporated into, for example, an ostomy pouch such as an ileostomy pouch, there is a consequential reduction in the possibility of blocking of the vent. Furthermore, if the vent of the pouch has a filter attached, then the life of the filter will also be extended.

The preservative or compounds having a similar effect as described above may also be used in conjunction with a binding species that binds to the chemical molecules that are attributable to the malodour. By binding to the binding species, the malodorous molecules are not detected as such by human nasal organs. Examples of binding species include those that are commonly used in litter beds for pet animals.

The term "preservative" as used in the present specification means a substance that prevents decay and decomposition of, for example, body fluids and other excretions. The preservative employed in the present invention can be any one or more of: a bacteriostatic agent, a bactericidal agent, an agent that changes water activity values of the *in situ* degradative enzymes (such as to inactivate such enzymes), or an agent that changes the pH of the excretion (such as to destroy the degradative enzymes). The term "agent" includes chemical compounds and derivatives thereof (e.g. free radical versions), and enzymes.

Preferably, the preservative is a water soluble compound. Typical chemical compounds for use as a preservatives in the present invention include sulphites, fluorides, nitrites, (e.g. sodium nitrite) nitrates, benzoates, (e.g. sodium benzoate) salicylates, borates and formaldehyde, and bactericides such as cationic surfactants such as benzalkonium chloride.

The preservatives usable in the invention are those which are capable of retarding the decomposition of the excretions. Typical preservatives are those commonly used in the food industry to preserve food before ingestion. Generally these preservatives inhibit gas production due to their bactericidal properties. Such food preservative, when in contact with wet or moist body excrement, will reduce the rate of decomposition of body waste materials.

The preservative when employed in the present invention will typically disperse/dissolve in the body waste.

The preservative can be incorporated into the formulation in the form of a liquid, powder or an aqueous solution.

According to a highly preferred embodiment of the present invention there is provided a method of treating body waste contained in an ostomy pouch, the method comprising contacting the body waste with a preservative and a water-swellaable polymer.

The advantages of this highly preferred embodiment, particularly when the ostomy pouch is an ileostomy pouch, include:

- a. significant reduction in the level of gases evolved in the pouch;
- b. when the pouch is emptied the contents will be less malodorous, and have a greater 'firmness' of composition, and hence be more patient friendly; and
- c. the gelled fluid will exhibit poor flow characteristics, and therefore if the pouch suffered from a defect, then the fluid excretions would not readily flow from the pouch.

If a filter device is attached to the vent of the ostomy pouch then there are the following additional advantages:

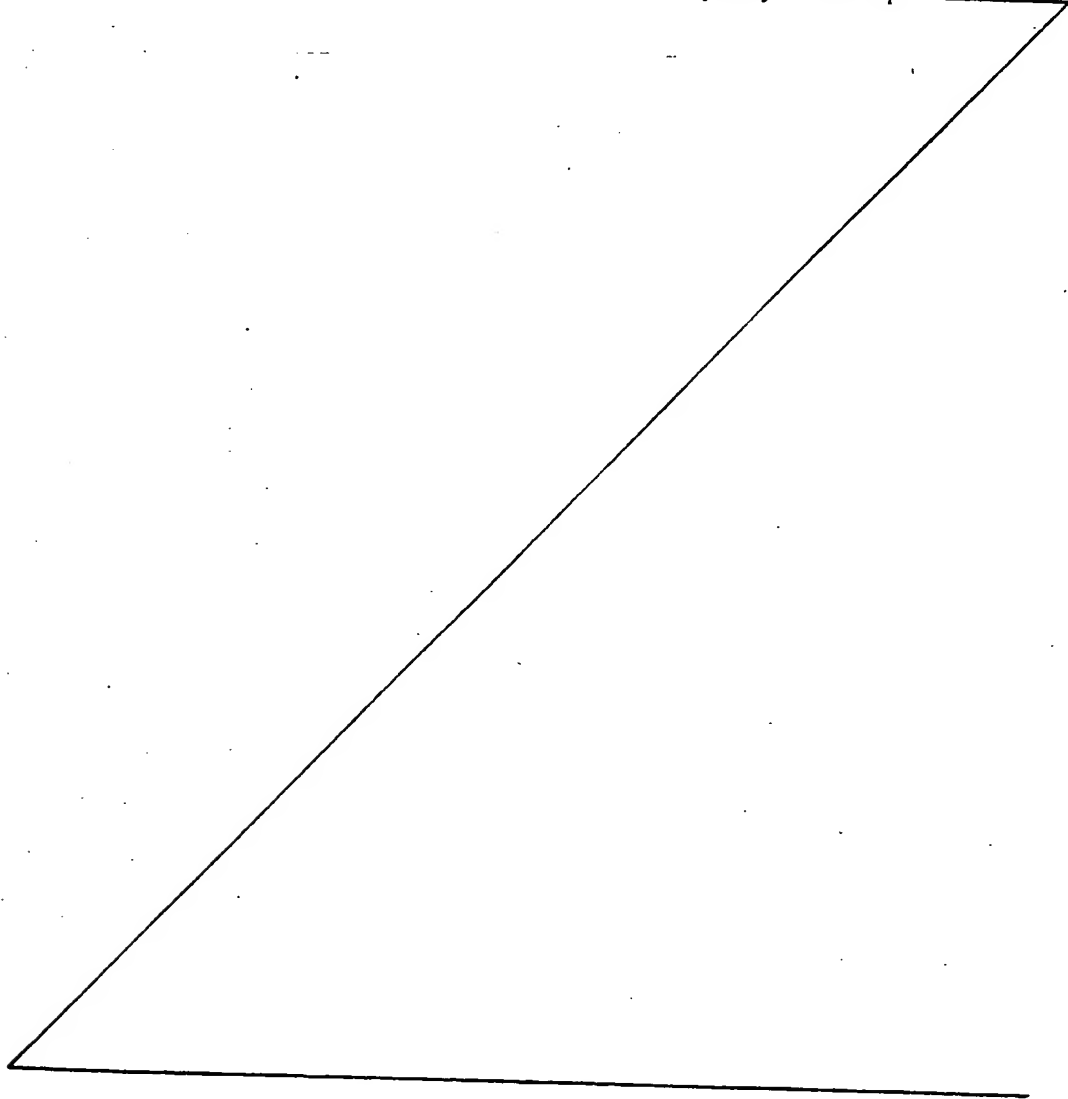
- a. the effective lifetime of the filter will be extended; and
- b. the filter will be significantly less susceptible to blocking by the

contained waste.

The invention in its preferred embodiments therefore solves the challenging problem of dealing with waste excreted by ileostomy sufferers.

5 A further aspect of the present invention is embodied in a method of treating body waste comprising contacting the body waste with a binding species (as aforesaid) and a water swellable polymer. In a preferred practical application, the formulation according to the present invention (i.e. swellable polymer and/or preservative and/or binding species) can be contacted with the wet or moist body excrement in either sheet or tablet form.

10 The present invention will now be described by way of example.



### EXAMPLE I

The composition of the formulation, in parts by weight (pbw), is advantageously:

- 100 parts by weight of a superabsorbent, water swellable polymer, e.g.
- 5 "SALSORB 90" (as supplied by Allied Colloids) which is a sodium polyacrylate,
- 0.5 to 6 pbw water,
- 6 to 15 pbw glycerol.

The processing method involves taking a formulated powder blend and pressing at about room temperature without addition of heat between two platens.

10 There is no other heating. The resultant product can have "skins" if so desired. Without "skins" the powder can be pressed into a tablet which may be any convenient thickness typically 10mm. When having upper and lower covering "skins" such as paper tissue the product will be a flat article whose thickness may typically be from 0.2mm to 4mm. The specific gravity of the finished product is typically in excess

15 of 1.0 and usually nearer 1.2. In this specification the term "skins" is used to mean a thin coherent layer, e.g. plastics film or paper tissue or non-woven fabric which serves to confine the formulated powder blend.

This process can be carried out using formulations in which superabsorbent powders are softened by a mixture of water and glycerol. The result is a powder

20 blend which can be compressed at low pressures and each particle of superabsorbent is bound into a structure, whereas in the absence of water and glycerol (or other polyhydroxy compound as described above), the structure will not retain its integrity unless a high force per unit area is utilised.

Also it is possible to incorporate into the powder blend of superabsorbent/

25 water/glycerol such materials as food preservatives, malodour counteractants etc. The end product can be cut without shedding particles. Other beneficial components which can be incorporated into such a tablet include:

- 5 - 50 pbw food preservative
- 2 - 15 pbw of tablet disintegrant
- 30 0 - 10 pbw of an internal mould release agent
- 0 - 30 pbw of an inert filler.

Some of these components assist in the processing of the tablet, and others in

its breakdown when contacted by wet or moist excrement.

### EXAMPLE II

A formulation comprising sodium polyacrylate 100 pbw, 0.5 to 6 pbw glycerol and 0.5 to 6 pbw water is mixed to a powder consistency in a conventional mixer 20 (see Figure 1 of the accompanying drawings), and is fed onto a travelling sheet 21 of tissue paper which is pulled off a supply roll 22. A second (overhead) sheet 23 of tissue paper is fed from a second supply roll 24 and these two sheets sandwich the powder between them. The product passes between a first pair of rolls 26 which form a first nip 27 and to a second pair of rolls 28 forming a second nip 29. The inter-roll spacing at the second nip 29 may be for example 1.0 to 2.0 mm. That at the first nip 27 may be 0.75 to 4 mm. No external heat is applied. The resulting product is a flat sheet which can then be cut into suitable shapes, e.g. rectangles 32, and can be directly placed in an ostomy pouch or incontinence pouch. It has been found to rapidly absorb a liquid such as urine. In tests, over 60 ml of synthetic urine were absorbed in under 60 seconds, usually under 40 seconds, by a product of one square centimetre area and 2 mm. thickness made by the method described above.

Reference has been made in the above specification to malodour counteractants. One example of a malodour counteractant is a bactericide, e.g. benzyl alkonium chloride. Another example is a fragrance. Other examples are included in a range of bactericides manufactured by ConvaTec (Calgon-Vestal Div.). Yet other malodour counteractants which may be used are methylchlorosiothiazolinone, methylisothiazolinone, or denatonium benzoate.

Other modifications in the present invention described above and in the method of performing the invention will be apparent to those skilled in the art without departing from the scope of the invention herein described and hereinafter claimed.

# CLAIMS

1. A formulation for use in the management of excreted body wastes, including, in parts by weight (pbw):-

5	superabsorbent	100pbw
	water	0.5 to 6pbw
	glycerol	5 to 30pbw.

2. A formulation according to claim 1 modified in that 6 to 15 pbw glycerol is present.

3. A formulation according to claim 1 or 2 in which the superabsorbent is sodium polyacrylate, and the particulate layer also includes one or more of:

- 15 a food preservative, and
- a malodour counteractant.

4. A formulation according to any one of claims 1-3 in which said article comprises a particulate layer which includes superabsorbent material sandwiched between upper and lower layers of plastics polymer film or woven or non-woven textile, or paper, e.g. tissue paper, with adhesive to join the layers if required, and in which the plastics polymer film is water-soluble or is weldable or is thermoformable.

5. A formulation according to any one of claims 1-4 disposed in an ostomy or incontinence pouch, in which the adhesive between the layers or any one of the layers is water soluble or water-dispersible whereby the pouch, if disposed of down a w.c., loses its structural integrity.

6. A pouch or container for waste products containing a formulation which is essentially 100 pbw superabsorbent, from 0.5 to 6 pbw water, from 5 to 30 pbw glycerol, from 0 to 5 pbw internal mould release agent, and from 0 to 50 pbw preservative.

7. A pouch according to claim 6 in which 6 to 15 pbw glycerol is present in the said flat article.
8. A pouch according to claim 6 or 7 in which the superabsorbent is a water-swelling polymer and is sodium polyacrylate, and in which the formulation includes one or more of:  
a preservative or compounds having a similar effect, and  
a malodour counteractant.
9. A pouch according to any one of claims 6-8 and including a formulation according to claim 4 in which the plastics polymer film is water-soluble, weldable, or thermo-formable.
10. A pouch according to any one of claims 6-9 in which the adhesive between the layers or any one of the layers is water soluble or water-dispersible, and in which the pouch when disposed of down a w.c. loses its structural integrity due to said solubility or dispersibility.
11. A bag according to claim 6 or 7 in which the superabsorbent is sodium polyacrylate and in which the formulation includes a food preservative.
12. A method of making a tablet or a flat article comprising:  
(i) providing a formulation comprising  
100 pbw superabsorbent,  
0.5 to 6 pbw water, and  
5 to 30 pbw glycerol; and  
(ii) pressing the said formulation without the application of heat between two flat platens at a pressure in the range 0.02 to 2 tonnes per sq. cm., with or without upper and lower confining sheets or films, or subjecting the formulation to a tableting operation.
13. A method according to claim 12 in which 6 to 15 pbw glycerol is present.

14. A method according to claim 13 in which the superabsorbent is sodium polyacrylate, and the particulate layer also includes one or more of:

a preservative, and  
a malodour counteractant.

15. A method of treating body excretions comprising contacting the excretions with a formulation which essentially comprises 100 parts by weight (pbw) superabsorbent, from 0.5 to 6 pbw water, from 5 to 30 pbw glycerol, from 0 to 5 pbw internal mould release agent, and up to 50 pbw preservative.

16. A method according to claim 15 wherein the formulation is in tablet form.

17. A method according to claim 16 in which the tablet also includes a tablet disintegrant, an internal mould release agent, and optionally, an inert filler.

18. A method according to any one of claims 14-17 wherein the preservative mainly comprises sodium benzoate and/or sodium nitrite.

19. A method according to any of claims 14-18, in which the superabsorbent comprises sodium polyacrylate.

20. A method according to any of claims 14-19 wherein the formulation includes 6 to 15 pbw of glycerol.

21. A formulation according to claim 3, or a pouch according to claim 8, or a method according to claim 14, in which the malodour counteractant is any one or more of: a fragrance, a bactericide, benzyl alkonium chloride, methylchlorosiothiazolinone, methylisothiazolinone, and denatonium benzoate.

22. An ileostomy pouch containing a preservative in conjunction with a superabsorbent water-swellaable polymer and glycerol.

23. A formulation for treating waste and the use thereof substantially as herein particularly described.

**Amendments to the claims have been filed as follows**

1. A formulation for use in the management of excreted body wastes, including, in parts by weight (pbw):-

5	superabsorbent	100pbw
	water	0.5 to 6pbw
	glycerol	5 to 30pbw.

2. A formulation according to claim 1 modified in that 6 to 15 pbw glycerol is present.

3. A formulation according to claim 1 or 2 in which the superabsorbent is sodium polyacrylate, and the particulate layer also includes one or more of:

- 15       a food preservative, and  
       a malodour counteractant.

4. A formulation according to any one of claims 1-3 in which said article comprises a particulate layer which includes superabsorbent material sandwiched between upper and lower layers of plastics polymer film or woven or non-woven textile, or paper, e.g. tissue paper, with adhesive to join the layers if required, and in which the plastics polymer film is water-soluble or is weldable or is thermo-

5. A formulation according to any one of claims 1-4 disposed in an ostomy or incontinence pouch, in which the adhesive between the layers or any one of the layers is water soluble or water-dispersible whereby the pouch, if disposed of down a w.c., loses its structural integrity.

6. A pouch or container for waste products containing a formulation which is essentially 100 pbw superabsorbent, from 0.5 to 6 pbw water, from 5 to 30 pbw glycerol, from 0 to 5 pbw internal mould release agent, and from 0 to 50 pbw preservative.

7. A pouch according to claim 6 in which 6 to 15 pbw glycerol is present in the said flat article.
8. A pouch according to claim 6 or 7 in which the superabsorbent is a water-swelling polymer and is sodium polyacrylate, and in which the formulation includes one or more of:
- a preservative or compounds having a similar effect, and
  - a malodour counteractant.
9. A pouch according to any one of claims 6-8 and including a formulation according to claim 4 in which the plastics polymer film is water-soluble, weldable, or thermo-formable.
10. A pouch according to any one of claims 6-9 in which the adhesive between the layers or any one of the layers is water soluble or water-dispersible, and in which the pouch when disposed of down a w.c. loses its structural integrity due to said solubility or dispersibility.
11. A bag according to claim 6 or 7 in which the superabsorbent is sodium polyacrylate and in which the formulation includes a food preservative.
12. A method of making a tablet or a flat article comprising:
- (i) providing a formulation comprising
    - 100 pbw superabsorbent,
    - 0.5 to 6 pbw water, and
    - 5 to 30 pbw glycerol; and
  - (ii) pressing the said formulation without the application of heat between two flat platens at a pressure in the range 0.02 to 2 tonnes per sq. cm., with or without upper and lower confining sheets or films, or subjecting the formulation to a tableting operation.
13. A method according to claim 12 in which 6 to 15 pbw glycerol is present.

14. A method according to claim 13 in which the superabsorbent is sodium polyacrylate, and the particulate layer also includes one or more of:

- a preservative, and
- a malodour counteractant.

5

15. A method of treating body excretions comprising contacting the excretions with a formulation which essentially comprises 100 parts by weight (pbw) superabsorbent, from 0.5 to 6 pbw water, from 5 to 30 pbw glycerol, from 0 to 5 pbw internal mould release agent, and up to 50 pbw preservative.

10

16. A method according to claim 15 wherein the formulation is in tablet form.

17. A method according to claim 16 in which the tablet also includes a tablet disintegrant, an internal mould release agent, and optionally, an inert filler.

15

18. A method according to any one of claims 14-17 wherein the preservative mainly comprises sodium benzoate and/or sodium nitrite.

20

19. A method according to any of claims 14-18, in which the superabsorbent comprises sodium polyacrylate.

20. A method according to any of claims 14-19 wherein the formulation includes 6 to 15 pbw of glycerol.

25

21. A formulation according to claim 3, or a pouch according to claim 8, or a method according to claim 14, in which the malodour counteractant is any one or more of: a fragrance, a bactericide, benzyl alkonium chloride, methylchlorosiothiazolinone, methylisothiazolinone, and denatonium benzoate.

30

22. An ileostomy pouch containing a preservative in an amount up to 50 pbw in conjunction with a 100 pbw superabsorbent water-swellaable polymer, glycerol in an amount from 5 to 30 pbw, and 0.5 to 6 pbw water.

23. A formulation for treating waste and the use thereof substantially as herein particularly described.



The  
Patent  
Office

17

Application No: GB 9612692.5  
Claims searched: 1-21, 23

Examiner: Roy Honeywood  
Date of search: 30 August 1996

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:  
UK CI (Ed.O): C1C (CACX CRCX CSCX CTCX)  
Int CI (Ed.6): C02F  
Other: ONLINE: WPI

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
	None	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

